DRAFT

STATE BOARD OF EQUALIZATION
STAFF LEGISLATIVE BILL ANALYSIS

Date Amended:	**As proposed**	Bill No:	**AB 71**
Tax:	**Drug Manufacturer Fee**	Author:	**Chan and Frommer**
Related Bills:			

This analysis will only address the bill's provisions that impact the Board.

BILL SUMMARY

This bill would require the Board of Equalization (Board) to annually assess and collect a fee on manufacturers of drugs sold in the state.

Summary of Amendments

Since the previous analysis, this bill was amended to incorporate many of the Board's suggested amendments necessary for the successful collection of the fee. Other amendments to the bill do not affect the Board.

Also, this bill is proposed to be amended to prohibit the Board from collecting fees in excess of the amount reasonably anticipated by the University of California to fully implement the Drug Safety and Effectiveness Program.

ANALYSIS

Current Law

Under existing law, a state and local sales and use tax is imposed on the sale or use of tangible personal property in this state, including prescription drugs, unless specifically exempted in the law. Section 6369, for example, provides an exemption for prescription medicines sold or furnished under specified conditions.

Currently, the total combined sales and use tax rate is between 7.25 and 8.75 percent, depending on the location in which the merchandise is sold. The Board does not collect any additional taxes or fees on the prescription drugs.

Proposed Law

This bill would add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 to the Health and Safety Code to enact the Drug Safety and Effectiveness Program.

Among other things, this bill would request the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in the state that would have the following components:

- A determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in the state.

- An Internet Web site that would report information on the safety and effectiveness of brand name and generic drugs in the classes, as identified, including, when available, direct comparisons of relative safety and effectiveness, and differential safety and effectiveness of specific drugs according to age, gender, race, or ethnicity.

This bill would also impose a fee on manufacturers of drugs sold in the state. The amount of the fee would be determined by the Department of Health Services (DHS), in consultation with the University of California, and would be limited to the amount necessary to fund the actual and necessary expenses of the university and its work in implementing the Drug Safety and Effectiveness Program. The total annual assessment on drug manufacturers would not exceed an amount not yet specified in the bill.

The specific fee to be assessed on a drug manufacturer would be established by the DHS, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state. A fee would not be assessed on a drug manufacturer that could demonstrate, as determined by the DHS, that it does not manufacture drugs that have described characteristics.

The fee would be assessed and collected annually by the Board in accordance with the Fee Collection Procedures Law (Part 20 (commencing with Section 55001) of Division 2 of the Revenue and Taxation Code). The Board would be authorized to prescribe, adopt, and enforce regulations, including, but not limited to, provisions governing collections, reporting, refunds, and appeals. The DHS would provide to the Board the name and address of each person or entity who is liable for a fee or expense, and related appeals.

The Board would not handle appeals or claims for refund if the petition or claim is founded upon the grounds that the DHS has improperly or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee. Those would be handled by the DHS.

The fees collected would be deposited into the Drug Safety and Effectiveness Program Fund (Fund), which this bill would established in the State Treasury. Moneys in the Fund would be expended, upon appropriation by the Legislature, for the purposes of the Drug Safety and Effectiveness Program, including the payment of refunds of the fee and to reimburse the Board for its administrative costs. All interest earned on the moneys deposited into the Fund would be retained in the Fund.

As proposed to be amended, this bill would prohibit the Board from collecting fees in excess of the amount reasonably anticipated by the University of California to fully implement the Drug Safety and Effectiveness Program.

This bill would become effective January 1, 2007.

COMMENTS

1. **Sponsor and purpose.** This bill is sponsored by the author and is intended to provide consumers more information on the safety and effectiveness of prescription drugs they are taking and thereby encourage them to discuss such information with their physicians.

2. **Summary of amendments.** The **proposed amendments** would prohibit the Board from collecting fees in excess of the amount reasonably anticipated by the University

of California to fully implement the Drug Safety and Effectiveness Program. Other proposed amendments, which would not affect the Board, are non-substantive, technical amendments.

The **June 22, 2006, amendments** incorporate many of the Board's suggested amendments necessary for the Board's successful collection of the fee. These amendments include, in part, that the Board would collect the fee pursuant to the Fee Collection Procedures Law, the DHS would provide to the Board the name and address of each person or entity who is liable for a fee or expense, and that the Board would not handle appeals or claims for refund if the petition or claim is founded upon the grounds that the DHS has improperly or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee.

The **June 7, 2006**, amendments require the Board to annually assess and collect a fee on manufacturers of drugs sold in the state. Previous versions of the bill did not impact the Board.

3. **Could the state require out-of-state retailers to remit a drug fee?** Various Supreme Court cases have focused on states' ability to impose the use tax on out-of-state firms making sales to in-state customers. In 1967 the Supreme Court ruled in *National Bellas Hess, Inc. v. Illinois Department of Revenue* (1967) 386 U.S. 753, that a firm that has no link to a state except mailing catalogs to state residents and filling their orders by mail cannot be subject to that state's sales or use tax. The Court ruled that these mail order firms lacked substantial physical presence, or nexus, required by the Due Process Clause and the Commerce Clause of the United States Constitution.

   In the 1977 case of *Complete Auto Transit, Inc. v. Brady* (1977) 430 U.S. 274 the Court articulated that, in order to survive a Commerce Clause challenge, a tax must satisfy a four part test: 1) it must be applied to an activity with a substantial nexus with the taxing State, 2) it must be fairly apportioned, 3) it does not discriminate against interstate commerce, and 4) it must be fairly related to the services provided by the State.

   North Dakota enacted anti-National Bellas Hess legislation with the expressed purpose of creating nexus with mail order firms selling to consumers in the state, in an attempt to compel out-of-state retailers to collect the use tax on mail order sales and test the continuing validity of the National Bellas Hess decision. The statute was challenged, and in 1992 the Supreme Court issued a ruling in Quill Corporation v. North Dakota (1992) 504 U.S. 298. The Court in Quill applied the Complete Auto Transit analysis and held that satisfying due process concerns does not require a physical presence, but rather requires only minimum contacts with the taxing state. Thus when a mail-order business purposefully directs its activities at residents of the taxing state, the Due Process Clause does not prohibit the state's requiring the retailer to collect the state's use tax. However, the Court held further that physical presence in the state was required for a business to have a "substantial nexus" with the taxing state for purposes of the Commerce Clause. The Court therefore affirmed that in order to survive a Commerce Clause challenge, a retailer must have a physical presence in the taxing state before that state can require the retailer to collect its use tax.

Based on the above cases, it is questionable whether the state could require an out-of-state manufacturer of drugs, who has no physical presence in California, to remit a fee.

4. **Suggested amendments.** As proposed to be amended, this bill would prohibit the Board from collecting fees in excess of the amount reasonably anticipated by the University of California to fully implement the Drug Safety and Effectiveness Program.

   However, it is not clear how the Board would know what the anticipated amount is for the University of California to implement the program when the bill requires that to be determined by the DHS and University of California. Or if the Board did know that amount, what would the Board's responsibility be if the DHS provides the Board with specific fees to be assessed on individual drug manufacturers that exceeds the amount for the University of California to implement the program? Would the Board only bill each drug manufacturer up to that determined amount for the university to implement, which would mean that some manufacturers won't be billed because it could exceed the implementation amount? This requirement appears inappropriately placed with the Board since the Board would simply bill and collect the fee based on information received from the DHS, which would determine the amount of the fees to be collected, in consultation with the University of California, and limited to the amount necessary to fund the actual and necessary expenses of the university and its work in implementing the Drug Safety and Effectiveness Program. The following amendment is suggested for the bill, as proposed to be amended:

   > 111657.1. (d) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this article. The ~~Board of Equalization~~ State Department of Health Services shall not ~~collect~~ establish specific fees pursuant to this section in excess of the amount reasonably anticipated by the University of California to fully implement this article.

   In addition, should the fees established be limited to the amount to implement the program or implement and fund on-going costs?

   And lastly, Section 111657(c)(2) provides that the DHS shall provide to the Board the name and address of each person or entity who is liable for a fee or expense, and related appeals. This provision should also require the DHS to provide the Board with the amount of the fee due from each drug manufacturer. It is also not clear what is meant by "and related appeals" since the Board would not handle appeals if the petition is founded upon the grounds that the DHS has improperly or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee. The following amendment is suggested:

   > 111657.1. (c)(2) The State Department of Health Services shall provide to the State Board of Equalization the name and address of each person or entity who is liable for a fee or expense and the amount of the fee~~, and related appeals~~.

   It is also suggested that this bill provide a due date for the drug manufacturer fee.

5. **This bill should contain a specific appropriation to the Board.** This bill proposes a fee to be imposed on or after January 1, 2007, which is in the middle of the state's fiscal year. In order to begin to develop computer programs and to hire

appropriate staff, an appropriation in the amount of $454,000 would be required to cover the Board's administrative start-up costs that are not identified in the Board's 2006-07 budget.

6. **Legal challenges of any new fee program might be made on the grounds that the fee is a tax.** In July 1997, the California Supreme Court held in *Sinclair Paint Company v. State Board of Equalization* (1997) 15 Cal.4th 866 that the Childhood Lead Poisoning Prevention Act of 1991 imposed bona fide regulatory fees and not taxes requiring a two-thirds vote of the Legislature under Proposition 13. In summary, the Court found that while the Act did not directly regulate by conferring a specific benefit on, or granting a privilege to, those who pay the fee, it nevertheless imposed regulatory fees under the police power by requiring manufacturers and others whose products have exposed children to lead contamination to bear a fair share of the cost of mitigating those products' adverse health effects.

   Although this measure has been keyed by the Legislative Counsel as a majority vote bill, opponents of this measure might question whether the fees imposed are in legal effect "taxes" required to be enacted by a two-thirds vote of the Legislature.

COST ESTIMATE

The Board would incur non-absorbable costs to adequately develop and administer a new fee program. These costs would include notifying feepayers, developing forms and publications, computer programming, mailing and processing determinations and payments, training staff, and answering feepayer inquiries.

Assuming that the Board would bill and collect the proposed fee from 300 drug manufacturers, and that the Board would develop its drug manufacturer fee collection program and assess and collect the fee during the 2006-07 fiscal year, these costs are estimated to be $454,000 for fiscal year 2006-07, $189,000 for fiscal year 2007-08, and $178,000 for fiscal year 2008-09, and each fiscal year thereafter. Any change to the assumptions could impact the estimated administrative costs.

REVENUE ESTIMATE

This measure does not specify the amount of the proposed fee. Accordingly, a revenue estimate could not be prepared.